Remarks

Claims 1, 4, 7-12, 23 and 28-33 are before the Examiner. Claims 1, 4, 7-12, 23, 30, 32, and 33 have been amended. Support for the claim amendments can be found throughout the application, including the claims as originally filed. Importantly, no new matter has been added to the claims. The amendments to the claims should not be construed to be an acquiescence to any of the rejections. The amendments to the claims are being made solely to expedite the prosecution of the above-identified application. Applicants reserve the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 USC § 120.

Applicants would like to thank Examiner Gembeh and her supervisory examiner, Examiner Christopher Low, for their time in conducting a phone interview with Applicants' representative. At the suggestion of Examiner Low, Applicants have amended claims 1, 4, 7-12, and 32 to be drawn to a pharmaceutical composition, and have amended claims 1, 9, 30, 32, and 33, such that the amount of hydroxyethyl cellulose and hydroxypropyl methyl cellulose affects the release rate of the pharmaceutically active substance.

The Examiner's remarks in the Office Action are addressed below.

Claim Rejections Under U.S.C. § 103(a)

Claims 1, 4, 7-12, and 28-33 stand rejected under 35 U.S.C. 103(a) based on the Examiner's contention that they are obvious over Guley et al., (U.S. Patent No. 4,309,405) in view of Jain et al., (U.S. Patent No. 4,610,870). The Examiner asserts that Guley et al. teaches a composition comprising both water soluble and water insoluble polymers, in particular, plural water soluble polymers including hydroxypropyl methyl cellulose (HPMC) and hydroxypropyl cellulose (HPC) and plural water-soluble polymers including ethylcellulose (EC) and carboxyvinyl cellulose. The Examiner also asserts that Jain et al. teaches the equivalence of HPC and hydroxyethyl cellulose (HEC) in the core. Applicants respectfully disagree with the Examiner. Applicants submit unexpected results showing that HEC is not equivalent to HPC over the weight percent range currently claimed.

Claims 1, 4, 7-12, and 28-33, as amended, are drawn to a controlled release pharmaceutical delivery composition comprising hydroxyethyl cellulose and hydroxpropyl

methylcellulose in amount of from 1% to 15% by weight. Applicants previously provided a Declaration in their response dated September 21, 2004, and include the Declaration again in the present response as Attachment 1, signed June 8, 2004 showing a comparison of a combination of HEC/HPMC of the claimed invention versus HPC/HPMC. The results shown in Table 2 and Figure 1 of the Declaration show significant differences between the release profiles of the two formulations. The amount of drug released in 1 hour is 38% for the HPC/HPMC combination, while the amount of drug released in 1 hour is only 28% for the HEC/HPMC combination. The difference between the two combinations increases with time. For example, the amount of drug released in 4 hours is greater than 90% for the HPC/HPMC combination, while the amount of drug released in 4 hours is less than 70% for the HEC/HPMC combination. Furthermore, it takes 5 hours to release 100% of the drug for the HPC/HPMC combination, while it takes 8 hours before 100% of the drug is released for the HEC/HPMC combination. These results show significant differences in the effect of drug release and availability of the two formulations and clearly indicate that HEC and HPC are not equivalent and interchangeable when used in combination with HPMC over the ranges presently claimed. The differences between the two formulations can impact the decision as to how often a product ought to be taken daily in order to be effective, which also impacts on patient compliance and wellness. These differences also impact adverse effects or safety especially for high potency drugs with low therapeutic indices.

Based on these submissions, the Applicants respectfully submit that an HPC/HPMC combination is not equivalent to an HEC/HPMC combination and, therefore, respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of the present claims.

Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicants' attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

Respectfully submitted,

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Date: January 11, 2007

Attachment 1

Attorney Docket SMI-005.01

Certificate of First Class Mailing

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450, on the date set forth below

September 21, 2004 By: Marissa Dorlich
Date of Signature and Mail Deposit

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Isa Odidi and Amina Odidi	:	Paper No.:
Serial No.	09/166,701	:	Group Art Unit: 1617
Filed:	October 5, 1998	:	Examiner: Webman, Edward J.
For:	**Controlled Release Pharmaceutical Delivery Device and Process For Preparation Thereof**		

DECLARATION UNDER 37 C.F.R. 1.132

Box Fee Amendment
Commissioner for Patents
Washington, DC 20231

Isa Odidi and Amina Odidi declare that:

1. They are co-inventors of and are familiar with the present U.S. Patent Application Serial No. 09/166,701, and they are familiar with the Official Actions issued in the present application and the reference cited by the Examiner; U.S. Patent No. 4,610,870 to Jain *et al.*

2. The controlled release pharmaceutical device and the pharmaceutical composition of the present invention comprise, amongst other components, hydroxyethylcellulose (HEC) and hydroxypropylmethyl cellulose (HPMC).

3. In order to demonstrate that hydroxyethylcellulose (HEC) and hydroxypropylcellulose (HPC) are not interchangeable when each are used with

hydroxypropylmethyl cellulose (HPMC), data is provided in Tables 1 and 2 and in Figure 1 for the HPC/HPMC combination compared to the HEC/HPMC combination.

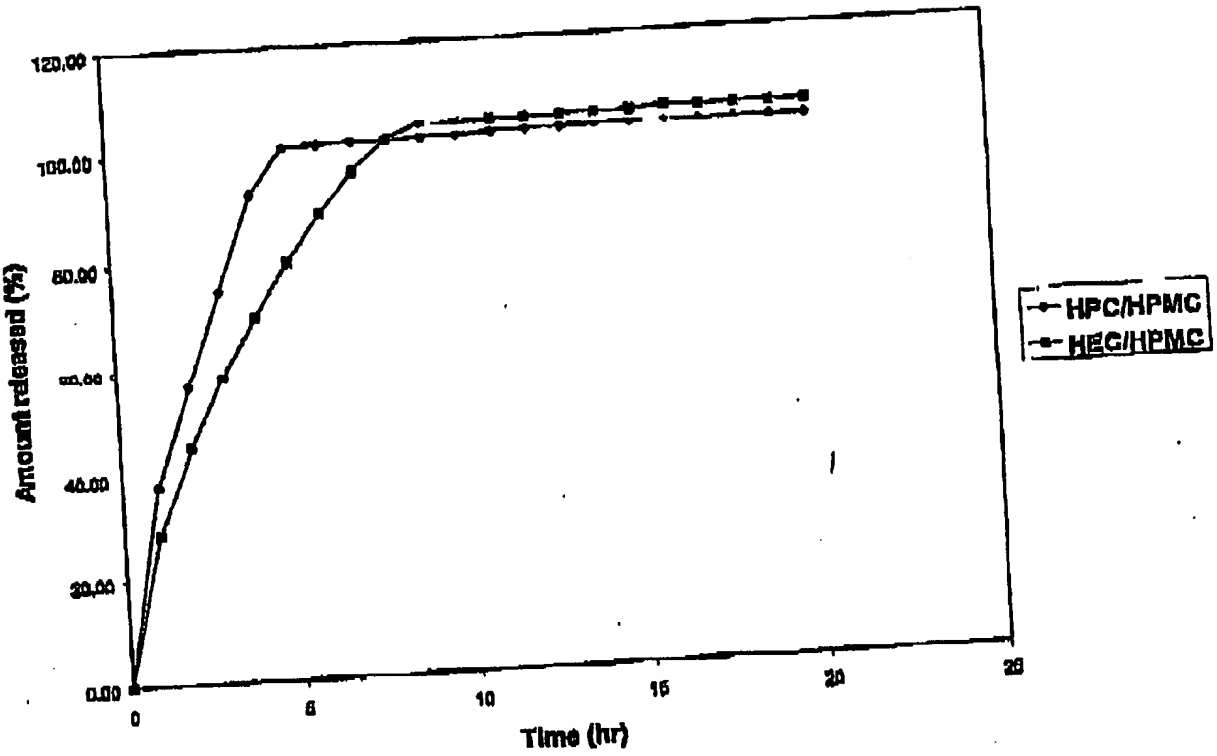
Table 1 Formulation of Model Drug using the Combination of HPC/HPMC vs. HEC/HPMC

Formulation	7.5% HPC and 7.5% HPMC	7.5% HEC and 7.5% HPMC
Model Drug	40%	40%
HPMC	7.5%	7.5%
HPC	7.5%	0%
HEC	0%	7.5%
Lactose	44%	44%
Magnesium Stearate	1%	1%

Table 2 Results from Dissolution studies of the Model Formulations

Time	7.5% HPC and 7.5% HPMC	7.5% HEC and 7.5% HPMC
0	0.00	0.00
1	38.03	28.71
2	56.72	45.27
3	74.81	58.44
4	92.49	69.71
5	100.67	79.9
6	100.97	88.46
7	101.09	95.75
8	101.09	101.33
9	101.39	104.77
10	101.50	104.59
11	101.86	104.71
12	102.10	104.89
13	102.27	105.07
14	102.45	105.18
15	102.51	105.30
16	102.69	105.66
17	102.81	105.68
18	102.87	105.86
19	102.93	105.86
20	102.93	105.66

Figure 1 Dissolution Profiles of Mixed Formulations



4. The results shown in Table 2 and Figure 1 show significant differences between the release profiles of the two formulations. The amount of drug released in 1 hour is 38% for the HPC/HPMC combination, while the amount of drug released in 1 hour is only 28% for the HEC/HPMC combination. The difference between the two combinations increases with time. For example, the amount of drug released in 4 hours is greater than 90% for the HPC/HPMC combination, while the amount of drug released in 4 hours is less than 70% for the HEC/HPMC combination. Furthermore, it takes 5 hours to release 100% of the drug for the HPC/HPMC combination, while it takes 8 hours before 100% of the drug is released for the HEC/HPMC combination.

5. These results show significant differences in the effect of drug release and availability of the two formulations and clearly indicate that HEC and HPC are not interchangeable when used in combination with HPMC.

6. The differences between the two formulations can impact the decision as to how often a product ought to be taken daily in order to be effective, which also impacts on patient compliance and wellness. These differences also impact adverse effects or safety especially for high potency drugs with low therapeutic indices.

7. Isa Odidi and Amina Odidi further declare that all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

June 8 2004

Isa Odidi

June 8 2004

Amina Odidi